

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

---

TAKEDA PHARMACEUTICAL CO, :  
LIMITED, et al. :  
Plaintiff, : Civil Action No. 10-1723 (JAP)  
v. :  
ZYDUS PHARMACEUTICALS :  
USA INC., et al. :  
Defendant. :  
:

---

This is an action for patent infringement brought by Plaintiffs Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals LLC, and Takeda Pharmaceuticals America, Inc. (collectively “Takeda” or “Plaintiffs”) against Zydus Pharmaceuticals (USA) Inc. (“Zydus”) and Cadila Healthcare Limited (“Cadila”) (collectively or “Defendants”) pursuant to the Hatch-Waxman Act, 21 U.S.C. § 355(j), alleging infringement of United States Patent Nos. 6,328,994 (the “‘994 patent”). A bench trial was held March 26 to April 1, 2013. For the reasons in the accompanying Opinion,

IT IS on this 7<sup>th</sup> day of May 2013

ORDERED as follows:

1. Judgment is entered in favor of Takeda against Zydus on Takeda’s claim of infringement of claim 1 of the ‘994 patent.
2. Judgment is entered in favor of Takeda on Defendants’ counterclaims seeking declarations of noninfringement and invalidity of the ‘994 patent.

3. The effective date of any Food and Drug Administration approval of Zydus's ANDA product that is the subject of this lawsuit shall be no earlier than the date of expiration for '994 patent and any pediatric exclusivity that applies to the '994 patent.

4. Zydus is hereby enjoined from engaging in the commercial manufacture, use, offer for sale or sale within the United States, or importation into the United States, of Zydus's ANDA product until expiration of the '994 patent.

/s/ Joel A. Pisano  
JOEL A. PISANO, U.S.D.J.